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In the Supreme Court of the United States

KATHLEEN SEBELIUS, ET AL.,
Petitioners,
v.
HOBBY LOBBY STORES, INC., ET AL.,
Respondents.

CONESTOGA WOOD SPECIALTIES CORP., ET AL.,
Petitioners,
v.
KATHLEEN SEBELIUS, ET AL.,
Respondents.

On Writs of Certiorari to the United States Courts of Appeals for the Tenth and Third Circuits

BRIEF OF NATIONAL HEALTH LAW PROGRAM, ET AL. AS *AMICI CURIAE* IN SUPPORT OF THE GOVERNMENT

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INTEREST OF THE AMICI[1]

The *amici curiae* are the National Health Law Program, American Public Health Association, National Family Planning & Reproductive Health Association, National Women's Health Network, National Latina Institute for Reproductive Health, National Asian Pacific American Women's Forum, Asian Americans Advancing Justice, Asian & Pacific Islander American Health Forum, Black Women's Health Imperative, Forward Together, National Hispanic Medical Association, Ipas, Sexuality Information and Education Council of the U.S. (SIECUS), HIV Law Project, Christie's Place, National Women and AIDS Collective, California Women's Law Center, and Housing Works. While each *amicus* has particular interests, they collectively bring to the Court an in depth understanding of the standards of care and existing federal laws that address the use and coverage of preventive reproductive health services. The *amici* want to bring accurate information on these topics to the Court as it considers the legality of the requirements for preventive health care services under § 2713(a)(4) of the Public Health Service Act, added by the Patient Protection and Affordable Care Act (ACA).

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[1] Counsel for Conestoga Wood Specialties Corp. and the Federal government have filed with the Clerk blanket consent to *amicus* briefs in this case. Counsel for Hobby Lobby Stores, Inc. consented to the filing of this brief. No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money to fund preparation or submission of this brief. No person, other than *amici* and *amici*'s counsel, contributed money intended to fund preparation or submission of this brief.

SUMMARY OF ARGUMENT

The ACA recognizes that preventive health services are critical to individual and community health. It accordingly requires new group health plans and health insurance issuers to cover such additional women's preventive health care services as provided for in guidelines supported by the Health Resources and Services Administration (HRSA).[2] By doing so, the ACA recognizes that women have unique reproductive and gender specific health needs.

Well-established standards of medical care and prevailing federal laws and policies predating the ACA recognize that family planning services are essential preventive care for women. The contraceptive coverage requirement adds to these larger federal policies and seeks to ensure that health plans sold in the individual and small group markets cover essential preventive services for women.

ARGUMENT

I. Accepted evidence-based standards of medical care recognize that contraception is essential preventive care for women.

This case concerns the ACA and United States Department of Health and Human Services' (HHS) requirement that most new health insurance plans cover women's preventive health services, including

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[2] *See* Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 1001, § 2713(a)(4), 124 Stat. 119, 131 (codified at 42 U.S.C. § 300gg-13(a)(4)).

contraception.[3] This requirement is in accord with accepted standards of medical care recognized by various professional medical academies and associations.

According to the American Medical Association's (AMA) Council on Ethical and Judicial Affairs, a standard of care is "'that level of care, skill and treatment' . . . which a 'reasonable and prudent [physician] similarly situated would provide under similar circumstances.'"[4] Standards are based on "information from clinical experience that has met some established set of validity, and the appropriate standard is determined according to the requirements of the intervention and clinical circumstance."[5] Researchers consider a variety of evidence in developing standards. Generally, standards are based on large quantities of evidence from empirical studies,

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[3] *See id.*; 45 C.F.R. § 147.130(a)(1); U.S. Dep't of Health & Human Servs. (HHS), Health Res. & Servs. Admin., Women's Preventive Services: Required Health Plan Coverage Guidelines, http://www.hrsa.gov/womensguidelines (last visited Jan. 21, 2014).

[4] Am. Med. Ass'n (AMA) Council on Ethical & Judicial Affairs, *Report of the Council on Ethical & Judicial Affairs* 12-A-04, at 3 (2004) (footnote omitted) (citations omitted) (defining standard of care in context of medical testimony in legal proceedings).

[5] LeighAnne Olsen et al., *The Learning Healthcare System: Workshop Summary (IOM Roundtable on Evidence-Based Medicine)* app. D 353, 354 (July 2011) (defining evidence).

but clinicians' practice experiences may also contribute to their development.[6]

Prevailing standards of medical care recognize family planning services as a necessary component of preventive care for women. These standards are reflected in the formal practice recommendations of health care professional associations such as the American Congress of Obstetricians and Gynecologists (ACOG), the Society of Family Planning, the American Academy of Pediatrics (AAP), the Society for Adolescent Medicine, the AMA, the American Public Health Association (APHA), and the Association of Women's Health, Obstetric and Neonatal Nurses, all of which "recommend use of family planning as part of preventive care for women."[7] For example, ACOG recommends that women have access to family planning services.[8] According to the American Academy of Family Physicians, effective contraceptive use is a

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[6] Nat'l Health Law Program, *Health Care Refusals: Undermining Quality Care for Women* 8 (2010) (defining standard of care).

[7] *See* Inst. of Med. (IOM) of the Nat'l Acads., *Clinical Preventive Services for Women: Closing the Gaps* 104 (2011) (citing Kay Johnson et al., *Recommendations to Improve Preconception Health and Health Care—United States: A Report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care*, 55 MORBIDITY & MORTALITY WKLY. REP. 1 (2006) (discussing practice guidelines)).

[8] *See, e.g.*, Am. Cong. of Obstetricians & Gynecologists (ACOG), *Technical Bulletin No. 205, Preconception Care*, 50 INT'L J. OF GYNECOLOGY & OBSTETRICS 201 (1995); ACOG Comm. on Gynecologic Practice, Comm. Op. No. 313, *The Importance of Preconception Care in the Continuum of Women's Health Care*, 106 OBSTETRICS & GYNECOLOGY 656, 656-66 (2005).

component of preconception care for all women who are not planning to become pregnant.[9] The APHA has endorsed universal access to contraception for over thirty years.[10]

Similarly, the United States Centers for Disease Control and Prevention's (CDC) Agency for Toxic Substances and Diseases Registry concludes that preconception (before pregnancy) and inter-conception (between pregnancies) care should include family planning counseling along with health insurance coverage of contraceptives, because, among other things, this coverage can reduce the risk of maternal and infant mortality and pregnancy-related complications.[11] The AMA supports these CDC recommendations.[12] These recommendations are particularly important for women of color who disproportionately experience chronic health conditions such as diabetes, heart disease, and obesity, all of which may be exacerbated by pregnancy.[13] In particular, these conditions underlie complications related to pregnancy or childbirth that contribute to

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[9] Michael C. Lu, *Recommendations for Preconception Care*, 76 AM. FAMILY PHYSICIAN 397, 399-400 (2007).

[10] Am. Pub. Health Ass'n, *Population: Family Planning as an Integral Part of Health Services*, Pol. No. 7518 (Jan. 1, 1975).

[11] Johnson et al., *supra* note 7, at 14, 17, 19-20.

[12] AMA House of Delegates, Policy No. H-425.976 (aff'd 2007).

[13] *See generally*, Kaiser Family Found., *Putting Women's Health Care Disparities on the Map: Examining Racial and Ethnic Disparities at the State Level* (2009).

the disproportionate maternal mortality rate among African American women.[14]

AAP and ACOG further recommend that every visit with a woman's clinician include a reproductive health screen and related counseling.[15] If pregnancy is not desired, AAP and ACOG standards call for the clinician and patient to discuss contraceptive options and proper use of the woman's chosen contraceptive method.[16] The discussion between the woman and her clinician is to "assist the [woman] in identifying the most appropriate and effective method for her" needs.[17]

A. Standards of care recommend effective contraceptive use for pregnancy spacing.

Unintended pregnancy is associated with poor health outcomes, maternal morbidity and mortality, and risky health behaviors. The World Health Organization's standards of care recommend that a woman space her pregnancies at least two years apart

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[14] *See generally*, D. Goffman et al., *Predictors of Maternal Mortality and Near-Miss Morbidity*, 27 J. PERINATOLOGY 597 (2007) (discussing racial disparities in maternal outcomes).

[15] Am. Acad. of Pediatrics (AAP) & ACOG, *Guidelines for Perinatal Care* 101 (7th ed. 2012); *see also* ACOG Comm. on Gynecologic Practice, *supra* note 8 (referring to guidelines for perinatal care and women's health care).

[16] *See* AAP & ACOG, *supra* note 15, at 101.

[17] *Id.*

so that her body can properly recover.[18] According to ACOG, women who become pregnant less than six months after their previous pregnancy are seventy percent more likely to have membranes surrounding the fetus rupture prematurely and are at a significantly higher risk of other complications.[19] Research also shows that short birth intervals are associated with higher than average rates of low birth weight and neonatal death.[20] Thus, the professional associations, including the AMA and ACOG, recommend that women have access to contraceptive counseling and services, which will enable them to appropriately space their pregnancies.[21]

B. Standards of care recommend that women taking drugs contraindicated for pregnancy have access to contraception.

Access to contraception is critical for women taking medications that pose serious risks for maternal and fetal health. A number of commonly prescribed pharmaceuticals are known to cause impairments in

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[18] Cicley Marston, World Health Org., *Report of a WHO Technical Consultation on Birth Spacing, Geneva, Switzerland, 13-15 June 2005*, at 2 (2007).

[19] Thomas Gellhaus, Statement of ACOG to the U.S. Senate, Comm. on Health, Educ., Labor & Pensions, Pub. Health Subcomm: Safe Motherhood (Apr. 25, 2002).

[20] *See, e.g.*, James S. Rawlings, *Prevalence of Low Birth Weight and Preterm Delivery in Relation to the Interval between Pregnancies among White and Black Women*, 332 N. ENG. J. MED. 69, 69 (1995) (citing studies).

[21] *See* discussion *supra* pp. 2-6.

the developing fetus or to create adverse health conditions for the pregnant woman.[22]

Approximately 11.7 million prescriptions for drugs, which the United States Food & Drug Administration (FDA) has categorized as Pregnancy Category D (there is evidence of fetal harm, but potential benefits may warrant use despite the harm) or Category X (contraindicated in women who are or may become pregnant because the risks of use of the drugs by a pregnant woman outweigh the potential benefits) are filled by significant numbers of women of reproductive age each year.[23] Approximately 5.8% of pregnancies in the United States are exposed to Category D or X drugs.[24] Multiple studies recommend that women of reproductive age who are taking these drugs use a reliable form of contraception to prevent pregnancy.[25]

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[22] David L. Eisenberg et al., *Providing Contraception for Women Taking Potentially Teratogenic Medications: A Survey of Internal Medicine Physicians' Knowledge, Attitudes and Barriers*, 25 J. GEN. INTERNAL MED. 291, 292 (2010); Susan E. Andrade et al., *Prescription Drug Use in Pregnancy*, 191 AM. J. OBSTETRICS & GYNECOLOGY 398, 406 (2004).

[23] Eleanor B. Schwarz et al., *Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women*, 147 ANNALS OF INTERNAL MED. 370, 370 (2007); Eleanor B. Schwarz et al., *Prescription of Teratogenic Medications in United States Ambulatory Practices*, 118 AM. J. MED. 1240, 1240-41 (2005).

[24] Eisenberg et al., *supra* note 22, at 291.

[25] *See, e.g., id.* at 291-92; Schwarz et al., *Documentation of Contraception*, *supra* note 23, at 374-75.

For example, Isotretinoin, a drug used to treat severe cystic acne, can cause multiple fetal impairments.[26] The FDA requires that women of reproductive age who are taking this drug agree to use two forms of contraception.[27] Iodine 131, which is used to treat hyperthyroidism and cancer, is another example of a drug for which pregnancy is contraindicated because it may destroy the developing fetus.[28] ACOG recommends that women taking Iodine 131 avoid pregnancy.[29]

C. Standards of care recommend that women with heart conditions have access to contraception.

Heart disease is the number one cause of death for women in the United States.[30] African American

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[26] Ctrs. for Disease Control & Prevention (CDC), *Accutane®-Exposed Pregnancies,* 49 MORBIDITY & MORTALITY WKLY. REPT. 28, 28 (2000).

[27] U.S. Food & Drug Admin., *iPledge Program Frequently Asked Questions as of July 21, 2006*, at 5 (2006), http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094313.pdf (last visited Jan. 23, 2014).

[28] ACOG on Practice Bulletins, *Practice Bulletin No. 37: Clinical Management Guidelines for Obstetrician—Gynecologists, Thyroid Disease in Pregnancy* (2002).

[29] *Id.*

[30] CDC, *Women and Heart Disease Fact Sheet* (Aug. 2013), http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/docs/fs_women_heart.pdf (last visited Jan. 21, 2014).

women have twice the age standardized rate of fatal incidence of cardiovascular disease as white women.[31] Hispanic and non-Hispanic Black women are also more likely to have multiple risk factors for heart disease, including high blood pressure, diabetes, and obesity.[32] There are a number of cardiac conditions, like valvular heart lesions, that are poorly tolerated given the physiological changes brought about during pregnancy.[33]

The American College of Cardiology and the American Heart Association Task Force on Practice Guidelines have issued specific recommendations for preconception management of women with valvular heart disease.[34] These guidelines recommend that management include provision of information about

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[31] Monika M. Safford et al., *Association of Race and Sex with Risk of Incident Acute Coronary Heart Disease Events*, 308 J. AM. MED. ASS'N 1768, 1772 (2012).

[32] Elsa-Grace V. Giardina, M.D. et al., *The DHHS Office on Women's Health Initiative to Improve Women's Heart Health: Focus on Knowledge and Awareness Among Women with Cardiometobolic Risk Factors*, 20 J. WOMEN'S HEALTH 893, 898 (Nov. 6, 2011).

[33] Robert O. Bonow et al., *2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease*, 118 CIRCULATION e523, e598-e604 (2008).

[34] Robert O. Bonow et al., *Guidelines for the Management of Patients with Valvular Heart Disease: Executive Summary A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Patients With Valvular Heart Disease)*, 98 CIRCULATION 1949, 1973 (1998).

contraception and maternal and fetal risks of pregnancy.[35] These professional associations recommend that clinicians counsel women with certain heart conditions, including valvular heart disease, against pregnancy.[36] The decision of whether to use contraception is, however, ultimately left to the woman.[37]

D. Standards of care recommend that women with diabetes have access to contraception.

Standards of medical care also advise women with diabetes to prevent pregnancy until their condition is under control. People with diabetes either produce insufficient insulin or cannot properly use insulin.[38] An estimated 10-18% of nonpregnant women of reproductive age have some type of abnormal glucose tolerance that carries maternal and fetal risks if they

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[35] *Id.* at 1974.

[36] Bonow et al., *2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease*, *supra* note 33, at e598-99.

[37] *See, e.g.*, AAP & ACOG, *supra* note 15, at 101 ("If pregnancy is not desired, current contraceptive use and options should be discussed to assist the patient in identifying the most appropriate and effective method for her.").

[38] CDC, *Diabetes and Pregnancy* (Sept. 4, 2012), http://www.cdc.gov/pregnancy/diabetes.html (last visited Jan. 24, 2014).

become pregnant.[39] Pregestational diabetes mellitus is a type of diabetes in women that develops before they become pregnant.[40] Pregestational diabetes is observed in about one percent of all pregnancies.[41] The type 2 diabetes prevalence rate is higher for women of color.[42] Moreover, "compared with non-Hispanic white adults, the risk of diagnosed diabetes was 18 percent higher among Asian Americans, 66 percent higher among Hispanics/Latinos, and 77 percent higher among non-Hispanic blacks."[43] Latinas also have higher rates of

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[39] Thomas Buchanan, *Pregnancy in Preexisting Diabetes*, DIABETES IN AM. 719, 720 (Nat'l Diabetes Data Group et al., eds., 2d ed. 1995).

[40] CDC, *Diabetes and Pregnancy*, *supra* note 38.

[41] ACOG Comm. on Practice Bulletins, *Practice Bulletin No. 60: Pregestational Diabetes Mellitus*, 105 OBSTETRICS & GYNECOLOGY 675, 675 (2005).

[42] U.S. Dep't of Health & Human Servs. (HHS), Nat'l Diabetes Info. Clearinghouse, Diabetes Overview, http://diabetes.niddk.nih.gov/dm/pubs/overview/#who (last visited Jan. 24, 2014); Ann S. Barnes & Stephanie A. Coulter, *The Epidemic of Obesity and Diabetes: Trends and Treatments*, 38 TEX. HEART INST. J. 142, 142 (2011).

[43] HHS, Nat'l Diabetes Info. Clearinghouse, *National Diabetes Statistics, 2011* (rev. Sept. 9, 2013), http://diabetes.niddk.nih.gov/dm/pubs/statistics/#Racial (last visited Jan. 21, 2014).

gestational diabetes than non-Hispanic white women, which puts them at greater risk for type 2 diabetes later in life.[44]

The failure to manage glucose levels during and before pregnancy can lead to serious complications and harm maternal and infant health.[45] For example, women with poorly controlled pregestational diabetes are at an increased risk of hypoglycemia, blindness, complications from chronic hypertension, and life-threatening complications from coronary heart disease.[46] Further, diabetic nephropathy—a significant complication of diabetes, the leading cause of renal failure, and a critical factor affecting pregnancy outcomes—affects six percent of pregnant women with type 1 diabetes.[47] The failure to manage glucose during preconception has been linked to malformations in infants and spontaneous abortion.[48]

The American Diabetes Association (ADA) and ACOG have issued standards of practice guidelines for preconception care for women with pregestational

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[44] Office on Women's Health, *Minority Women's Health: Diabetes* (updated May 18, 2010), http://womenshealth.gov/minority-health/latinas/diabetes.html (last visited Jan. 21, 2014).

[45] ACOG Comm. on Practice Bulletins, *Practice Bulletin No. 60*, *supra* note 41, at 676-77.

[46] *Id.* at 677-78.

[47] E. Albert Reece et al., *Pregnancy in Women with Diabetic Nephropathy*, UptoDate (Dec. 3, 2012).

[48] Am. Diabetes Ass'n (ADA), *Preconception Care of Women with Diabetes*, 26 DIABETES CARE S91, S91 (2003).

diabetes. According to the ADA, "planned pregnancies greatly facilitate preconception diabetes care."[49] The ADA standards of care for women with diabetes with childbearing potential include: (1) "use of effective contraception at all times, unless the patient is in good metabolic control and actively trying to conceive" and (2) counseling about the risk of fetal impairment associated with unplanned pregnancies and poor metabolic control.[50] ACOG recommends that women have glucose levels under control before becoming pregnant to decrease the likelihood of spontaneous abortion, fetal malformation, and fetal or infant death.[51]

E. Standards of care recommend that women with lupus have access to contraception.

Contraception is a critical service for women with lupus. Lupus is an auto-immune disorder, which can affect multiple parts of the body, including skin, joints, blood, and kidneys and that has multiple end-organ involvement.[52] Often called a "woman's disease," nine

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[49] ADA, *Standards of Medical Care in Diabetes – 2006*, 36 DIABETES CARE S11, S44 (2013).

[50] *Id.*

[51] ACOG Comm. on Practice Bulletins, *Practice Bulletin No. 60*, *supra* note 41, at 681.

[52] HHS, Office on Women's Health, *Lupus: Frequently Asked Questions* 1-2 (June 13, 2011), http://www.womenshealth.gov/publications/our-publications/fact-sheet/lupus.pdf (last visited Jan. 24, 2014).

out of ten people with lupus are women.[53] The incidence rate for lupus is two to three times higher for African American women than for Caucasian women.[54] Lupus is also more common in women of Latina, Asian, and Native American decent.[55] Women with lupus who become pregnant face particularly increased risks of health complications.[56] A large review of United States hospital data found that the risk of maternal death for women with lupus is twenty times the risk for pregnant women without lupus.[57] Women with lupus are three to seven times more likely to suffer from thrombosis, infection, renal failure, hypertension, and preeclampsia.[58]

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has issued a standard of care recommending that women with lupus take these health risks and complications into consideration in determining whether to become pregnant or to carry a pregnancy to term and that

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[53] *Id.* at 2.

[54] *Id.*

[55] Nat'l Inst. of Arthritis & Musculoskeletal & Skin Diseases, *Handout on Health: Systemic Lupus Erythematosus* (2013), http://www.niams.nih.gov/Health_Info/Lupus/ (last visited Jan. 22, 2014).

[56] *Id.* at 11; *see, e.g.*, Megan E. B. Clowse et al., *A National Study of the Complications of Lupus in Pregnancy*, 199 AM. J. OBSTETRICS & GYNECOLOGY. 127.e1, 127.e3 (2008).

[57] Clowse et al., *supra* note 56, at 127.e3.

[58] *Id.* at 127e.1, e.3-e.4.

physicians counsel women to use contraception until their condition is under control.[59] Because of the multiple and life-threatening risks associated with lupus, NIAMS recommends that women delay pregnancy until there are no signs or symptoms of lupus.[60] The NIAMS standard accordingly instructs women with lupus to use contraception: "Do not stop using your method of birth control until you have discussed the possibility of pregnancy with your doctor and he or she has determined that you are healthy enough to become pregnant."[61] The CDC's clinical guidance similarly concludes that unintended pregnancy presents an unacceptable health risk for women with lupus and, therefore, recommends that clinicians advise women with lupus that using only barrier or behavior-based methods of contraception may not be appropriate.[62]

Practice guidelines are clear: women require information about and access to contraceptives to prevent pregnancy. By requiring new group health plans and health insurance issuers to cover women's preventive care services, the ACA recognizes that women have unique reproductive and gender-specific

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[59] Nat'l Inst. of Arthritis & Musculoskeletal & Skin Diseases, *Lupus: A Patient Care Guide for Nurses and Other Health Professionals* 45-47, Patient Info. Sheet Nos. 4-5 (3d ed. 2006).

[60] *Id.* at Patient Info. Sheet No. 11.

[61] *Id.* at Patient Info. Sheet No. 4.

[62] CDC, *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*, 59 MORBIDITY & MORTALITY WKLY. REPT. 4, 6 (2010).

health needs.[63] HHS' decision to adopt the IOM's recommendation that women receive coverage for all FDA-approved methods of contraception free of cost-sharing comports with well-established standards of medical care.[64]

II. Contraceptive coverage is widely required through federal laws and policies predating the ACA.

The ACA and HHS coverage provisions reflect a long history of federal legislation which requires coverage of preventive contraceptive counseling, services, and supplies. In 1973, Congress enacted the Health Maintenance Organization (HMO) Act to encourage the delivery of health care through the HMO model.[65] The Act applies to private health plans that apply for federal qualification, a designation that enables HMOs to, among other things, avoid state laws more restrictive than the HMO Act.[66] The HMO Act identifies basic health services that HMOs must

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[63] 42 U.S.C. § 300gg-13(a)(4).

[64] *See* 45 C.F.R. § 147.130(a)(1); HHS, Health Res. & Servs. Admin., *supra* note 3.

[65] Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, § 1, 87 Stat. 914, 914 (1973) (codified at 42 U.S.C. §§ 300e-300e-17); *see also* S. Rep. No. 93-129, at 3037-41 (1973) (stating purpose of Act to "provide assistance and encouragement for the establishment and expansion of health maintenance organizations").

[66] 42 U.S.C. §§ 300e (defining HMO as a "public or private entity"), 300e-5 (application requirements), 300e-10 (stating that restrictive state laws do not apply to federally qualified HMOs).

provide.[67] "Basic health services" include "family planning services."[68]

The Federal Employees Health Benefits (FEHB) program also covers family planning services. The FEHB program provides employee health benefits to civilian government employees and annuitants of the United States government.[69] The United States Office of Personnel Management contracts with qualified private insurance carriers to offer health care plans through the FEHB program.[70] As part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Congress approved a "contraceptive equity provision" requiring most FEHB plans to cover contraception.[71] Accordingly, the United States Office of Personnel Management requires all FEHB plans to cover the full range of FDA-approved

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[67] 42 U.S.C. § 300e-1.

[68] 42 U.S.C. §§ 300e-1(1)(H)(iv) (defining "basic health service"), 300e (requiring HMO to cover "basic and supplemental health services").

[69] *See* 5 U.S.C. §§ 8901-8914 (health insurance for government employees), 8905(a)-(b) (defining eligible persons).

[70] *Id.* § 8902; *Muratore v. U.S. Office of Pers. Mgmt.*, 222 F.3d 918, 920 (11th Cir. 2000) ("Congress enacted the FEHBA . . . to create a comprehensive program of subsidized health care benefits for federal employees and retirees."); U.S. Office of Pers. Mgmt., *The Fact Book, Federal Civilian Workforce Statistics* 82 (2007), http://www.opm.gov/feddata/factbook/ (last visited Jan. 24, 2014).

[71] Omnibus Consolidated & Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 656(a), 112 Stat. 268, 530 (1998).

contraceptive drugs and devices.[72] As amended in 1998, the FEHB program includes specifically enumerated religious health plans that do not have to cover contraception, and authorizes inclusion of future plans objecting to such coverage "on the basis of religious beliefs."[73] However, the decision of whether to take up contraceptive coverage is left to the employee, who can choose from up to 300 plans, most of which cover contraception.[74] This coverage, then, is different from a refusal clause that would allow any employer to opt out of providing female employees preventive health care benefits because of the employer's religious beliefs. Unlike the FEHB program, such a proposal would leave employees without plan options that include preventive care coverage.

Federal legislation regulating health services available to military personnel and their families also requires coverage of preventive contraceptive services. Congress established a military health system "to create and maintain high morale in the uniformed services by providing an improved and uniform

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[72] U.S. Office of Pers. Mgmt., Benefits Admin. Ltr. No. 98-418 (Nov. 6, 1998).

[73] Pub. L. No. 105-277, § 656(b), 112 Stat. 268, *supra* note 71; *see also* Cong. Research Servs., *Laws Affecting the Federal Employees Benefits Program (FEHBP)* (Feb. 13, 2013), https://www.fas.org/sgp/crs/misc/R42741.pdf (last visited Jan. 22, 2014).

[74] U.S. Office of Pers. Mgmt., *Federal Employees Health Benefits Program Patients' Bill of Rights and the Federal Employees Health Benefits Program*, http://www.opm.gov/insure/archive/health/billrights.asp#Choice (last visited Jan. 21, 2014).

program of medical and dental care for members and certain former members of those services, and for their dependents."[75] Pursuant to congressionally delegated authority, the Department of Defense established the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) in 1967 (now known as TRICARE).[76] In 1995, the Department of Defense established TRICARE as a "comprehensive managed health care program for the delivery and financing of health care services in the Military Health System."[77] TRICARE provides health care benefits to active-duty service members, retirees and their families, and other beneficiaries from any of the seven services.[78] TRICARE offers all beneficiaries a range of FDA-approved methods of contraception, including intrauterine devices, diaphragms, prescription contraceptives, and surgical sterilization.[79]

Congress' declaration of a national policy of "ensur[ing] the highest possible health status for

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[75] 10 U.S.C. § 1071.

[76] Pub. L. No. 85-861, § 1(25)(B), 72 Stat. 1450 (1958), amended by Pub. L. No. 89-614, § 2(1), 80 Stat. 862 (1966) (codified at 10 U.S.C. §§ 1071-1110b).

[77] 32 C.F.R. §§ 199.17(a), 199.3; 10 U.S.C. § 1073(2).

[78] *See* 10 U.S.C. §§ 1072 (defining TRICARE), 1074 (providing for medical and dental care for members and certain former members of armed forces), 1077 (providing for medical and dental care for dependents).

[79] 32 C.F.R. § 199.4(e)(3); 10 U.S.C. § 1077 (preventive health care services for women includes pregnancy prevention).

Indians and urban Indians" also includes the requirement that health plans cover family planning services and supplies.[80] Among other things, Congress authorized the Secretary of HHS, acting through the Indian Health Service (IHS), "to provide health promotion and disease prevention services to Indians . . . ."[81] Congress' definition of "health promotion" includes programs for "reproductive health and family planning."[82] According to the Indian Health Manual, IHS "provide[s] comprehensive family planning services to all eligible American Indian and Alaska Native men and women."[83] This includes, "[a]ll available Food and Drug Administration (FDA) approved types of contraceptive (mechanical, chemical and natural) methods," with the individual deciding the appropriate choice of method.[84]

Coverage of family planning services and supplies is also a requirement of Medicaid—the country's largest public health insurance program covering approximately sixty million low-income people.[85] States

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[80] 25 U.S.C. § 1602(1)-(2).

[81] 25 U.S.C. § 1621b(a).

[82] 25 U.S.C. § 1603(11)(G)(xix).

[83] HHS, Indian Health Serv., *Indian Health Manual* § 3-13.12B(1), http://www.ihs.gov/ihm/index.cfm (last visited Jan. 21, 2014).

[84] *Id.* at §§ 3-13.12F(2), 3-13.12B(1).

[85] *See* 42 U.S.C. § 1396d(a)(4)(C); *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990) ("Although participation in the program is voluntary, participating states must comply with certain

participating in Medicaid receive significant federal funding in return for providing specified health coverage to specified groups of people (with a state option to cover additional groups and services). The Medicaid Act requires participating states to cover family planning services and supplies for all categorically needy beneficiaries.[86]

The ACA's contraceptive coverage provision builds upon this existing body of federal law. Standards of medical care recognize that a woman's ability to use contraception is critical to her health and well-being. The federal government has long-recognized these standards of medical care by enacting laws and policies that ensure women's access to health insurance benefits that include contraception coverage.

III. Federal law seeks to ensure that private health insurance coverage adequately meets women's health care needs by requiring coverage of contraception.

In its petition for a Writ of Certiorari, Hobby Lobby Stores., Inc. argued that the federal government can achieve its contraceptive access goals through other "readily available means," highlighting Title X of the

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requirements imposed by the Act and regulations."); Kaiser Family Found., *Medicaid: A Primer* 1 (Mar. 2013).

[86] 42 U.S.C. § 1396d(a)(4)(c); 42 C.F.R. § 441.20; *see* Ctrs. for Medicare & Medicaid Srvs. (CMS), *State Medicaid Manual* § 4270; CMS, *Dear State Medicaid Director* (July 2, 2010) (discussing family planning related services in context of new eligibility option under ACA § 2303).

Public Health Service Act (Title X).[87] *Amici* accordingly briefly address the interplay between the ACA provision at issue and Title X.

The ACA seeks to increase the quality and affordability of health insurance through a number of mechanisms, including the establishment of a minimum level of "essential health benefits" in health insurance coverage.[88] Among other things, Congress added § 2713(a)(4) of the Public Health Service Act to ensure that women receiving coverage through private insurance—a "group health plan" or from "a health insurance issuer offering group or individual health insurance coverage"—have a minimum level of coverage of preventive health services necessary to preserve and maintain women's health.[89]

Title X, on the other hand, is the nation's only dedicated source of federal funding for safety net family planning services.[90] While Title X health centers can provide care to all patients, federal law requires them

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[87] Br. of Respondents at 34-35, *Sebelius v. Hobby Lobby Stores, Inc.*, No. 13-354 (Oct. 21, 2013).

[88] *See e.g.*, 42 U.S.C. § 300gg-6(a) (requiring individual or small group market health plans to cover a package of "essential health benefits"); 42 U.S.C.§ 18022(b)(1) (listing ten categories of "essential health benefits").

[89] 42 U.S.C. § 300gg-13(a)(4).

[90] *See* 42 U.S.C. §§ 300-300a-8; HHS, Office of Population Affairs, *Title X Funding History*, http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/title-x-funding-history/ (last visited Jan. 22, 2014).

to give priority to "persons from low-income families."[91] In addition to being low-income, Title X patients are also disproportionately people of color. In 2012, of the approximately 4.8 million Title X family planning users, thirty one percent self-identified as black or African American, Asian, Native Hawaiian or Pacific Islander, or American Indian or Alaska Native, and twenty eight percent self-identified as Hispanic or Latino.[92]

Safety net programs like Title X are not designed to absorb the unmet needs of higher-income, insured individuals. Furthermore, Title X is designed to subsidize a program of care, not pay all of the cost of any service or activity—the Title X statute and regulations contemplate how Title X and third party payers will work together to pay for care, directing Title X-funded agencies to seek payment from such third party payers.[93] Even more, Title X is already underfunded and overburdened. Between the 2010 and 2012 fiscal years, Title X funding decreased by

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[91] 42 C.F.R. § 59.5(a)(6)-(9).

[92] Christina Fowler, et al., *Title X Family Planning Annual Report: 2012 National Summary* ES-2 (rev. Dec. 2013) http://www.hhs.gov/opa/pdfs/fpar-national-summary-2012.pdf (last visited Jan. 22, 2014).

[93] *See e.g.*, 42 U.S.C. § 300a-4(c)(2) (prohibiting charging persons from a "low-income family" for family planning services "except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge"); 42 C.F.R. § 59.5(a)(7), (9).

approximately twenty-four million dollars, or 7.4%.[94] This time period also corresponds with the largest decrease in the number of patients served in Title X sites in more than a decade.[95]

Title X and similar programs seek to ensure preventive services for primarily low-income and uninsured individuals who rely on publicly funded safety net programs for access to services. Even with the ACA's expansion of health insurance coverage, the U.S. Congressional Budget Office estimates that approximately 30 million nonelderly individuals will remain uninsured in 2016.[96]

CONCLUSION

Standards of medical care recommend that women have access to contraception as a necessary part of critical preventive health care services. The contraceptive coverage provision at issue here makes this access possible by ensuring that health plans in the individual and small group market adequately

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[94] *See* HHS, Office of Population Affairs, *supra* note 90; *see also* Nat'l Campaign to Prevent Teen and Unplanned Pregnancy, *Summary of Federal Funding Relevant to Teen and Unplanned Pregnancy Prevention* 2 note (m) (2012), http://www.thenationalcampaign.org/policymakers/PDF/FY2010-2013_Appropriations.pdf (last visited Jan. 23, 2014).

[95] Christina Fowler et al., *supra* note 92, at ES-1.

[96] Cong. Budget Office, *Payments of Penalties for Being Uninsured Under the Affordable Care Act* 1 (2012), http://www.cbo.gov/publication/43628 (last visited Jan. 22, 2014).

cover services that ensure women's health and well-being. This Court should find for the Government and uphold the contraceptive coverage provision.

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